510(k) Summary of Safety and Effectiveness
K123889

MAR 4 2013

I. General Information

Submitter: Theravant Corporation
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USA

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Summary Preparation Date: December 17, 2012

II. Names

Trade Names: Acleara System; TheraClear System

Primary Classification Name: Laser Powered Surgical Instruments

K Number: K123889

III. Predicate Device(s)

- TheraClear System (K101415);

IV. Product Description

The Theravant System is comprised of the following main components:

- Main console
- Treatment Handpiece(s)

The Theravant System is a portable tabletop system used to deliver intense pulsed light to the patient treatment site via a delivery handpiece utilizing vacuum technology. Intense pulsed light

is emitted through the tip only when the tip is sealed against the selected patient treatment site. All emitted light is contained within the tip during treatment.

A modification to the handpiece includes a needle accessory for use during the treatment of inflammatory acne lesions. The modified handpiece does not introduce any changes to the principles of operation as compared to the traditional handpiece. The modified handpiece uses vacuum to confine and stretch the target region, coupled with a fine gauge needle to facilitate the release of sebum from the pilosebaceous unit.

V. Indications for Use

The device modification does not affect the indications for use, although the modified handpiece is recommended for use in conjunction with the treatment of acne lesions only.

The Theravant Acleara System is intended for:

- The treatment of benign vascular and pigmented lesions;
- Permanent hair reduction;
- The treatment of mild to moderate acne, including pustular acne, comedonal acne, and mild to moderate inflammatory acne (acne vulgaris).

The TheraClear System is intended for use on all skin types (Firzpatrick types I-VI).

VI. Rationale for Substantial Equivalence

The Acleara modified handpiece insert is substantially equivalent to the Acleara Original handpiece inserts. The basis for the insert modification is a simple means to facilitate the release of sebum from the pilosebaceous unit. To a large extent, this is currently achieved during the vacuum process employed by the Acleara system. Using the same principal as traditional lancing or manual extraction of sebum, the modified insert employs a fine gauge needle to ease the release of sebum during the vacuum process. The use of the modified insert is intended as a complimentary procedure to the current recommended Acleara treatment for acne.

VII. Safety and Effectiveness Information

The review of the indications for use and technical characteristics demonstrates that the Acleara System is substantially equivalent to the predicate device. Performance testing, including validation and verification testing, and risk analysis support the support the safety and effectiveness of the modification.

VIII. Conclusion

The Handpiece Modification to the Theravant Acleara System does not present new or different risks. The indications for use, device operation, overall technical and functional capabilities remain the same and therefore is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Theravant, Corporation
% Ms. Marcy Moore
Regulatory Consultant
131 Kelekent Lane
Cary, North Carolina 27518

Letter dated: March 4, 2013

Re: K123889
Trade/Device Name: Acleara/Theraclear
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: ONF
Dated: January 22, 2013
Received: February 04, 2013

Dear Ms. Moore:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): **K123889**

Device Name: Acleara/TheraClear

Indications for Use:

The Theravant Acleara/TheraClear System is intended for the treatment of benign vascular and pigmented lesions; permanent hair reduction; and the treatment of mild to moderate acne, including pustular acne, comedonal acne, and mild to moderate inflammatory acne (acne vulgaris), in all skin types (Fitzpatrick I-VI).

Prescription Use ✓ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden -S
2013.02.28 15:06:29 -05'00'

(Division Sign-Off) for MXM
Division of Surgical Devices
510(k) Number K123889